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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,690

04/19/2004

Valerie Legrand

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01/07/2009

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EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,690	<b>Applicant(s)</b> LEGRAND ET AL.	
	<b>Examiner</b> Leah Schlientz	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgement of Receipt***

Applicant's Response, filed 1/28/08, in reply to the Office Action mailed 7/27/07, is acknowledged and has been entered. Claims 11 and 23 have been cancelled. Claims 1-10, 12-22 and 24 have been amended. Claims 1-10, 12-22 and 24 are pending and are examined herein on the merits for patentability.

### ***Priority***

In view of the Decision on Petition Under 37 CFR 1.78(a)(3) mailed 12/24/2008 dismissing the petition filed on 10/27/2006 to accept an unintentionally delayed claim under 35 U.S.C. § 120 for the benefit of priority to the prior-filed nonprovisional application set forth in the amendment filed 10/27/2006, the priority date for the instant application is considered to be the filing date of the instant application, or 4/19/2004, because a proper chain of priority has not been established.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 5/15/08 was filed after the mailing date of the Office Action on 7/27/07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Response to Arguments***

Applicant's arguments filed 1/28/08 have been fully considered. Any rejections not reiterated herein have been WITHDRAWN.

***Double Patenting***

Claims 1-10, 12-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/492,129. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth in the previous Office Action. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***New Grounds for Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ

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1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe compound B and, accordingly, the identification/description is indefinite.

Applicant argues that the names of the claims trademarks are proper because their meanings are well known in the literature.

This is not found to be persuasive. In particular, the claims refer to trademarks when referring to compound B. The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. See MPEP 608.01(v).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Legrand (FR 2,830,447, published 4/11/2003, whereby US 2005/0037077 is relied upon as equivalent for English language translation).

Legrand discloses microparticulate oral galenical form for the delayed and control release of at least one AP--excluding perindopril--this AP having an absorption window in vivo that is essentially limited to the upper parts of the gastrointestinal tract, said form being designed so as to guarantee its therapeutic efficacy by guaranteeing its absorption in vivo, and being characterized in that: the release of the AP is governed by two different triggering mechanisms, one being based on a variation in pH and the other allowing the release of the AP after a predetermined residence time in the stomach, and its dissolution behavior in vitro (determined as indicated in the European Pharmacopeia, 3rd edition, under the title: "Dissolution test for solid oral forms": type II dissolutest performed under SINK conditions, maintained at 37.degree. C. and agitated at 100 rpm) is such that: at a constant pH of 1.4, the dissolution profile includes a latency phase with a duration less than or equal to 5 hours, preferably of between 1 and 5 hours, and the change from pH 1.4 to pH 6.8, during the latency phase, results in a release phase that starts without a latency period (paragraphs 0081 – 0085). The particles of AP each coated with at least one film, this coating film consisting of a composite material which comprises: at least one hydrophilic polymer A

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carrying groups that are ionized at neutral pH, and at least one hydrophobic compound B; and represents a mass fraction (% by weight, based on the total mass of the microcapsules) of  $\leq 40$ ; and have a diameter below 2000 microns, preferably of between 200 and 800 microns and particularly preferably of between 200 and 600 microns, characterized in that their coating film consists of a composite based on A and B in which the weight ratio B/A is between 0.2 and 1.5, preferably between 0.5 and 1, and the hydrophobic compound B is selected from products that are crystalline in the solid state and have a melting point  $T_{fB}$  such that  $T_{fB} \leq 40$ .degree °C (paragraphs 0088 – 0096). Hydrophilic polymer A may be methacrylic acid, cellulose derivatives, etc. (paragraph 0097 – 0101). Compound B may be vegetable waxes, etc. (paragraph 0102 – 0106), including those marketed under the tradename Dynasan 116, etc. (paragraph 103). With regard to instant claims 7-10, which further comprise a second compound, Legrand discloses mixtures of compound B, including hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil and mixtures thereof; monoesters and/or diesters and/or triesters of glycerol with at least one fatty acid, preferably behenic acid, etc. (paragraph 0102-0106). At a constant pH of 1.4, the controlled release phase following the latency phase is such that the release time for 50% by weight of the AP ( $t_{1/2}$ ) is defined as follows (in hours):  $0.5 \leq t_{1/2} \leq 20$  (paragraphs 0123 – 0125). Preferably the AP is deposited on a neutral core, which may be sucrose and/or dextrose and/or lactose, or it can consist of a cellulose microsphere (paragraph 0132). The AP may be the AP is selected from the following compounds: metformin, acetylsalicylic acid, amoxicillin, pentoxifyllin, prazosin,

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acyclovir, nifedipine, diltiazem, naproxen, etc. (paragraph 0142). The microparticulate oral galenical form according to the invention can be a tablet, advantageously a tablet that disperses in the mouth, a powder or a gelatin capsule (paragraph 0143).

Applicant argues that as Applicant stated in the December 5, 2007 interview, a Petition to Accept an Unintentionally Delayed Claim was filed on January 28, 2008 and should correct the priority, setting the priority date for the instant application to be October 9, 2001. As such, this rejection is obviated and Applicant respectfully requests the rejection be withdrawn.

This is not found to be persuasive in view of the Petition decision mailed 12/24/2008 dismissing Applicant's Petition to Accept an Unintentionally Delayed Claim.

### ***Conclusion***

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

LHS